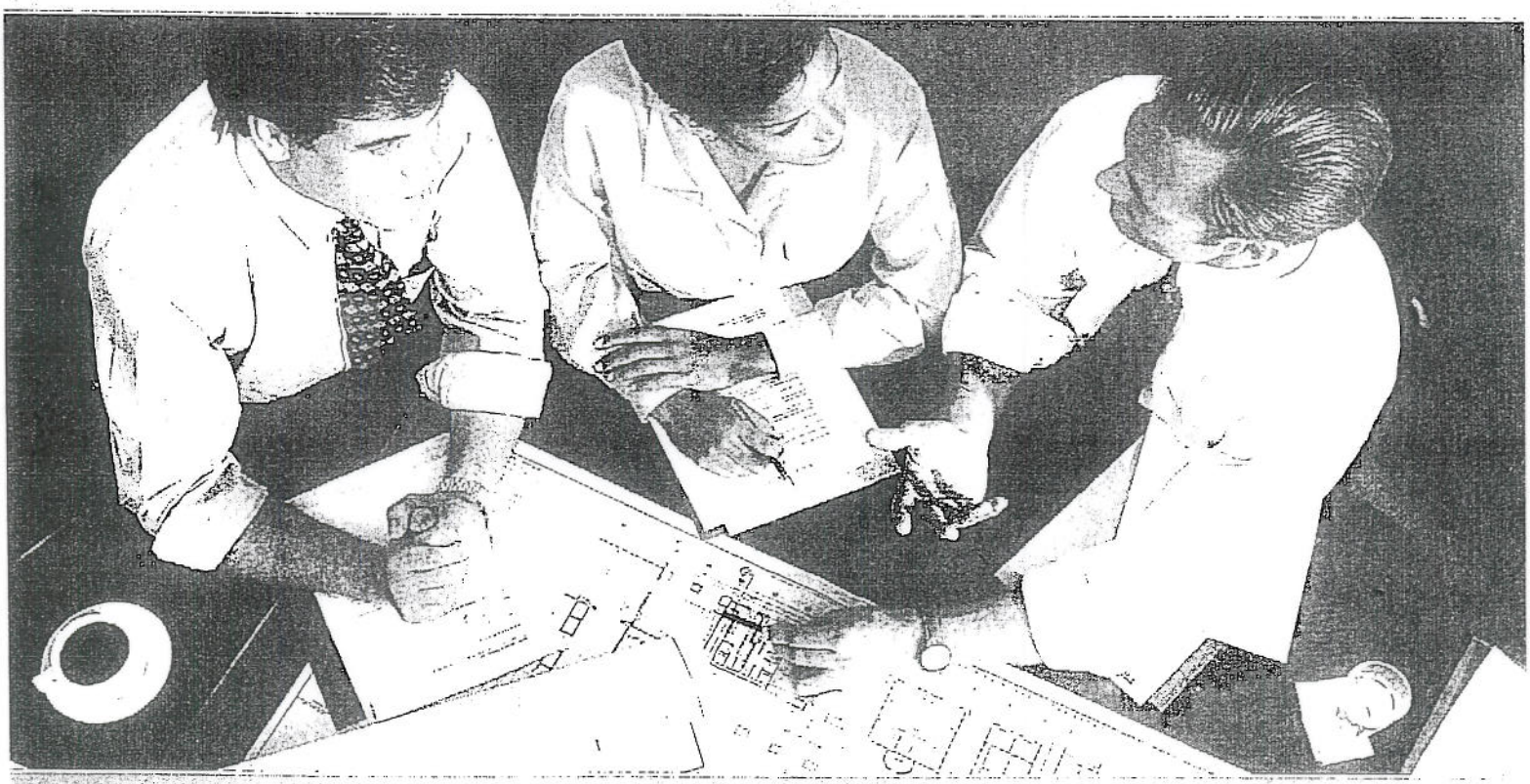
POLICY ECONOMICS INNOVATION

OPEI Regulatory Development Series

EPA's Action Development Process

Guidelines for Preparing Analytic Blueprints



EPA's Action Development Process

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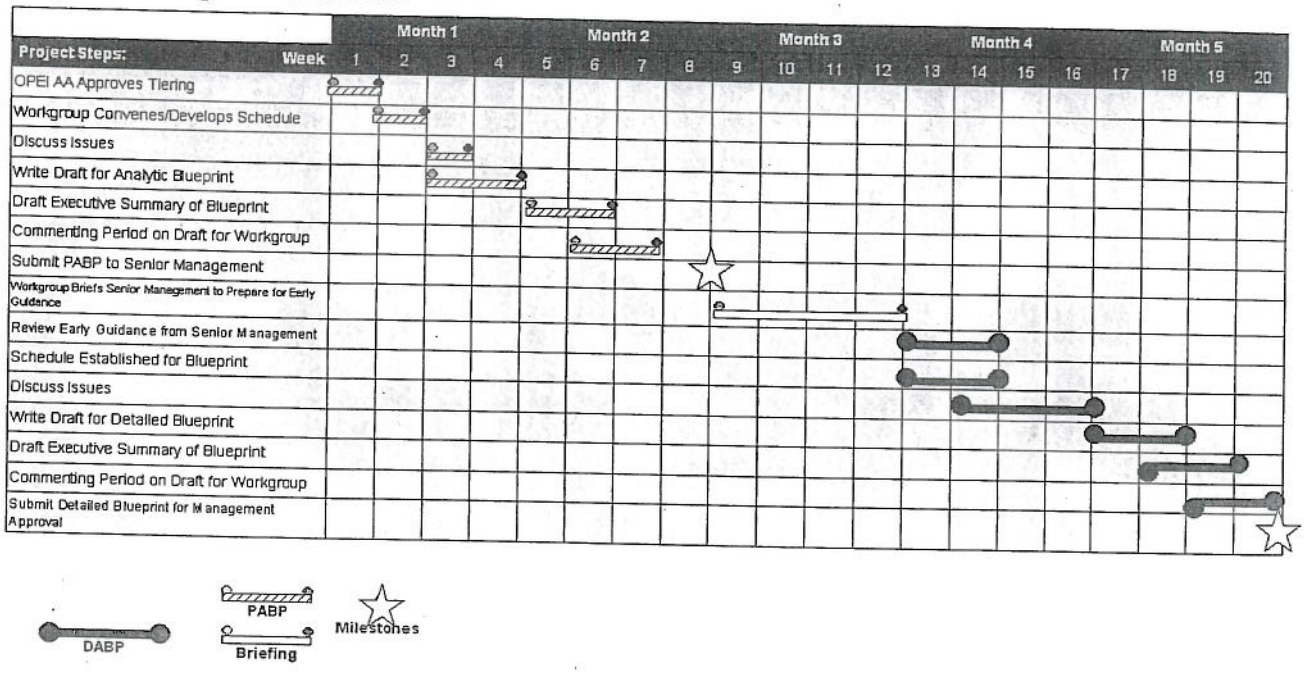
Project Development Schedule



This document identifies internal Agency policies and recommended procedures for EPA employees who are participants or managers developing or reviewing an Analytic Blueprint for a particular action. As indicated by the use of non-mandatory language such as "guidance", "recommend", "may", "should", and "can", it identifies policies and provides recommendations and does not impose any legally binding requirements.

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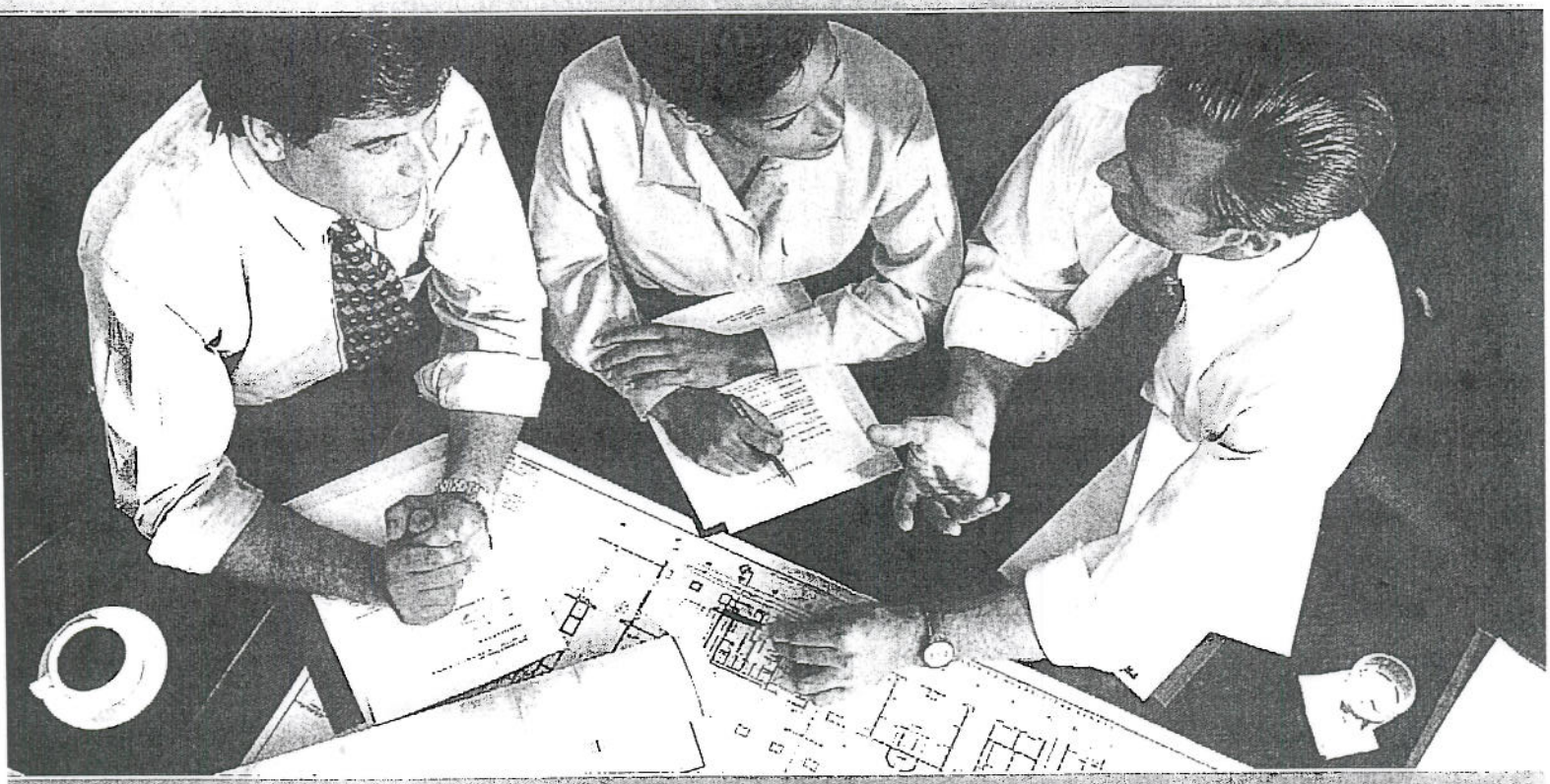

How to Use This Guidance

This guidance describes the purpose and content of Analytic Blueprints used in EPA's Action Development Process (ADP). It discusses the timing and steps for the drafting and approval of Analytic Blueprints and lets you know where to go for more information and guidance. It is applicable to all Tier 1 and 2 actions that are tiered under the Action Development Process after the date of issuance and for actions that have already been tiered but for which substantial work on the analytic blueprint has not taken place. For all other Tier 1 and 2 actions you should use the 1994 Analytic Blueprint Guidance (see http://intranet.epa.gov/adplibrary).

This guidance is intended to be sufficiently flexible to apply to many different kinds of actions, but as you go through it you may decide, in consultation with the workgroup, that certain parts of it are not relevant to your action. The Guidance presents many analytic questions to consider, though the workgroup should use its judgment about which questions are relevant and how much detail is appropriate in any given case. The point to remember is that the analytic blueprint process is intended to be a useful planning tool in early action development. The blueprint process facilitates cross-agency discussion, engages management early on and guides action development.

Before you begin work on your blueprint you should understand that it is a two-phased process intended to facilitate the development of your action. The first phase, **the preliminary analytic blueprint,** is essentially an early planning document intended to help the workgroup organize itself, identify potential data and analytic needs, and present an initial path to final action. It will serve as the mechanism for getting early guidance from management. There is no formal approval process for the preliminary blueprint. Any issues on which the workgroup cannot reach agreement should be identified and discussed as part of the early guidance process.

The **detailed analytic blueprint** expands upon the information compiled during the preliminary blueprint phase. The detailed blueprint incorporates early senior management input and establishes a common plan for developing information needed to inform eventual regulatory policy choices. To help focus the workgroup, the detailed analytic blueprint undergoes a formal approval process similar to the current Final Agency Review process. Once your analytic blueprint is approved, you can continue to update or amend your blueprint as necessary. Since the ABP is a "living document" the workgroup, in consultation with management, can modify the blueprint throughout the process as necessary. If used in this fashion the blueprint will ultimately facilitate your work and improve your final work product.

Your office may also have program specific procedures that apply to the development of your Analytic Blueprint. In developing the Analytic Blueprint for your action, you should consult your Regulatory Steering Committee (RSC) representative or Regional Regulatory Contact (RRC) to learn what specific procedures apply to your office and to advise you on any questions you may have on this guidance.

We've tried to keep this guidance concise and readable and we're developing additional implementation tools to help you. We'd like to know if we've succeeded and welcome your comments and suggestions on the guidance. Please route any comments through your Regulatory Steering Committee Representative or your Regional Regulatory Contact.

Table of Contents

I. What Are Analytic Blueprints?

This section explains the purpose and use of Analytic Blueprints, including critical elements to guide a successful Blueprint process. The section also briefly discusses the rationale and notable revisions incorporated in this guidance.

A. What is the Purpose of an Analytic Blueprint?

Analytic Blueprints (ABPs or Blueprints) are one critical part of EPA's Action Development Process (ADP)[1]. The ADP is designed to ensure EPA develops and issues quality rules, policy statements, guidance documents, Reports to Congress, and other regulatory and non-regulatory actions[2]. Likewise, the ultimate purpose of Analytic Blueprints is to enhance the quality of EPA actions[3].

A Blueprint spells out a workgroup's plans for the *data collection and analyses* that will support development of a specific action. The Blueprint sets forth how this information will be collected, peer reviewed, and used to craft the action within a specific budget and time frame. In addition, the Analytic Blueprint expands EPA's opportunities to consider a broad range of possible regulatory (and non-regulatory) strategies, including alternative or innovative approaches that complement traditional methods[4]. A Blueprint improves an action by

1. facilitating cross-Agency sharing of valuable information, expertise, and perspectives, and fostering early agreement on key questions through a structured workgroup process and written document; and

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[1]The Agency's Action Development Process Guidance is available online at http://intranet.epa.gov/adplibrary.

[2]Hereafter, references to "actions" are intended to include regulatory and non-regulatory actions.

[3]See *Improving Regulations*, 2001 Task Force Report.

[4]Innovative approaches could also be considered in other stages, including workgroup data collection, stakeholder consultation, and response to public comment after a rule has been proposed. However, it is most beneficial and feasible to consider alternative approaches early in the development of an action.

2. guiding the workgroup to plan for all the required data and analytic needs.

The term "analyses" is used very broadly here to include all qualitative discussions and thought processes that help EPA decide how the action should be designed. Analysis is not limited to economic or scientific data, but also encompasses assessment of legal, policy, stakeholder, and compliance-related information. Agreement on the Blueprint up-front, by managers across the Agency, significantly reduces the likelihood of issues being raised at the end of the process.

B. How do Preliminary and Detailed Blueprints Differ?

To best accomplish the goals of the Analytic Blueprint, Blueprints are developed in two phases: a Preliminary Blueprint (P-ABP) and a Detailed Blueprint (D-ABP). This two-phase process is meant to:

- Facilitate early cross-office participation,
- Identify critical path (i.e., ensure appropriate sequencing) of supporting analyses early in action development to help ensure appropriate analyses and information are available in a timely manner,
- Align expectations of participating workgroup members and their managers about the workgroup effort and scope of analysis, and
- Provide an agreed upon framework for writing a quality action.

The Preliminary Blueprint serves four primary purposes:

1. **Promotes management involvement** by supporting early management guidance[5] on basic issues such as:
   - rationale for the action,
   - overall approach and range of options to be considered (e.g. requirements, incentives, education, etc.),
   - budgetary requirements (e.g. contractor support),
   - staff resources, and
   - legal, scientific, economic or policy considerations;
2. **Alerts the workgroup members and the offices** they represent to areas where work should begin;
3. **Identifies what data are needed** and the potential sources for that data; and
4. **Serves as the foundation** for the Detailed Blueprint.

[5]See *Early Guidance* in EPA Action Development Process Guidance (http://intranet.epa.gov/adplibrary).

The level of detail included in a Preliminary Blueprint varies, sometimes significantly. For highly regulated industries, EPA may already know much about the environmental problem to be addressed and the industry sector affected. In such cases, the Preliminary Blueprint should reflect what is already known about the particular environmental problem and recognize current efforts aimed at mitigating any negative impacts. For relatively new regulatory areas, EPA may be less familiar with the environmental context at the outset. In these cases, the Preliminary Blueprint may be a mere outline of what is known or planned.

The Detailed Blueprint expands upon the Preliminary Blueprint and serves four related purposes:

1. **Incorporates senior management guidance** received on the Preliminary Blueprint;
2. **Alerts management and various offices** to any important issues that have arisen since the Preliminary Blueprint;
3. **Helps the workgroup** plan the details of analysis (which options to analyze and how, what data to gather and how, etc.) and schedule that analysis. This planning should be done with a view to presenting the analytic results at the Options Selection[6] meeting. Furthermore, it helps ensure the analysis will follow EPA guidance and policies, as well as satisfy the various Statutes and Executive Orders (EOs) which may apply to the particular action; and
4. **Documents agreement** among workgroup participants and management on the Blueprint's scope and analytic framework.

The degree of revisions expected from Preliminary to Detailed Blueprint may vary by section. Some sections will likely not change at all (e.g., Rationale and Legal Issues sections), some will need to reflect changes in the substantive document (e.g., Introduction and Regulatory Approaches sections), and others may need to be completely rewritten or filled in with additional details (e.g., Executive Summary and Analytic and Outreach sections).

C. What Makes an Analytic Blueprint Effective?

Blueprints facilitate collaboration and development of well-supported and documented actions. Several elements are believed to contribute significantly to a successful Blueprint process. These elements, provided below, help Blueprints avoid becoming merely paperwork exercises. They enhance the workgroup process and help avoid the workgroup being bogged down by last-minute debates over the type of information or analyses that should have been developed.

1. *Involvement* of all workgroup members to incorporate various perspectives and expertise, including those beyond the lead office staff.

[6]Ibid

2. *Early* discussion and documented agreement to increase accountability, establish workgroup member expectations, and avoid costly last-minute disruptions or delays. This includes *explicit opportunities for management input* (e.g., supports "early guidance").
3. *Targeted, succinct* presentation focused on the key analytic issues; and sufficient detail to allow substantive input on the analytic information to be developed.
4. *Clear roles and deadlines* to set the tone for effective, timely group work. A schedule of what information is needed, including who will get it and analyze it, to ensure that the appropriate information is available at key decision points (e.g., Early Management Guidance, Option Selection and Final Agency Review[7]).

To be most useful, the Analytic Blueprint is completed early in the process before key decisions are made, i.e., before significant analysis begins. This ensures necessary resources are allocated by participating offices to carry out the work and significant analyses are structured to inform option development and ultimately Option Selection[8] (e.g., allowing inclusion of an additional option in a risk assessment[9] or regulatory impact analysis[10]; or use of different modeling approaches). It is particularly important to address any "critical path" issues as early as possible to ensure adequate time to develop or gather appropriate data and conduct the necessary analysis. Also, you should ensure that the information used to inform the decision meets the objectives of the Agency's Information Quality Guidelines, including peer review. For example, you may need to specifically identify possible distributional effects that need to be considered in the risk assessment (such as estimated risks to children or other subpopulations). Timely drafting and approval allow the Blueprint to achieve its purposes of highlighting key analytic decisions, encouraging early management involvement, and promoting thoughtful input from the cross-office participants on the workgroup.

D. When is an Analytic Blueprint Expected?

EPA expects that workgroups on all Tier 1 and Tier 2 actions[11] will submit and obtain approval of Analytic Blueprints at the appropriate times during action development (see approval process and timing discussions below). Blueprints continue to be strongly recommended for Tier 3 actions and certain program offices have made this a regular practice.

E. Why was this Guidance Prepared?

Those familiar with the previous Analytic Blueprint guidance (1994) will need to review this guidance document carefully. This guidance incorporates lessons from nine years of experience with Analytic Blueprints, which provided useful insights into areas that worked well

[7]See EPA Action Development Process Guidance (http://intranet.epa.gov/adplibrary).

[8]See EPA Action Development Process Guidance (http://intranet.epa.gov/adplibrary).

[9]See "Guidance on Cumulative Risk Assessment: Part 1-Planning and Scoping" (http://www.epa.gov/osp/spc/2cumrisk.htm).

[10]See "NCEE's Guidelines for Preparing Economic Analyses" (http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html) and OMB's Circular A-4 (http://www.whitehouse.gov/omb/circulars/a004/a-4.html).

[11]See EPA Action Development Process Guidance (http://intranet.epa.gov/adplibrary)

and areas that could be improved. In addition, the guidance reflects changes or renewed areas of focus in the Action Development Process.

The Agency's experience with Analytic Blueprints has been mixed. One program found the Blueprint process to be a useful framework and asked its staff to develop Blueprints for Tier 3 actions, as well as Tier 1 and Tier 2. However, in many parts of the Agency, Blueprints were viewed as paperwork exercises that yielded little value and so were not used by senior managers, were never completed (or even started), or provided little information other than a checklist of statutory, regulatory, or Executive Order assessments to be addressed in the eventual *Federal Register* notice.

This Guidance reaffirms EPA's commitment to early planning and Analytic Blueprints. A successful Blueprint process and document helps ensure:

- Early policy guidance from senior managers;
- Clear articulation of a "critical path" to timely information development;
- A range of alternatives, including innovative options;
- Thoughtful consideration of resource requirements (e.g., FTE and contract dollars);
- A well functioning workgroup/team and cross-office participation; and
- No late surprises or "late hits" in the process.

F. What is New in this Guidance?

This guidance document differs from earlier guidance in some key ways:

Two Phases: Previously, Blueprints were described as "living documents" developed in an iterative process. This guidance describes a two-phase Blueprint development process[12]:

- Preliminary Blueprints (a planning document prepared very early); and
- Detailed Blueprints (an extended version of the earlier document, with more information, produced later in the action development process).

Content: This guidance describes the expected content of Blueprints more explicitly, to ensure they serve a clear purpose.

Timeline: Additional milestones and focus on timing/milestones to help workgroups plan timely completion of Blueprints.

Approval Process: The approval process is detailed.

[12]It may still be useful to revise/update the Blueprint during the rule-development process as new information becomes available and priorities change.

II. What Is Included in an Analytic Blueprint?

This section describes the heart of the Analytic Blueprint. It provides an outline for Blueprints and discusses the information that should be included under each section. The outline is the same for the Preliminary and Detailed Blueprint. However, the level of detail will be different and the formally approved Detailed Blueprint will serve as the operating framework for conducting analysis and outreach to inform the eventual decision regarding the specific elements of the action.

Outline of an Analytic Blueprint

The same basic outline applies to both the Preliminary and Detailed Blueprints because the Detailed Blueprint is an expansion and update of the Preliminary document:

A. Executive Summary (1 page)
   - Rationale, overall approach, resource implications, other management-level issues

B. Introduction (1-2 pages)
   - Summary of important points (including background)
   - Extent of Agency discretion
   - Rationale for the action

C. Types of Regulatory and Non-regulatory Approaches (1-2 pages)
   - Type of action
   - Scope of action

D. Analysis and Outreach (5-15 pages total, assuming 1 to 3 pages per section)
   a. Scientific Issues
   b. Economic Issues
   c. Stakeholder Involvement
   d. Legal Issues
   e. Implementation, Enforcement, and Compliance
   f. Other Key Topics

E. Workgroup Members and Contact Information

F. Schedule for Action Under Development

A. Executive Summary

The executive summary should be succinct and written with senior management as the target audience. Typically, the executive summary will be the last section written so it can summarize the plans and decisions discussed in the body of the Blueprint. The executive summary should pull together a bulleted list of regulatory and non-regulatory options expected to be analyzed and presented in the Options Selection meeting[13]. It should also include, for reference, basic pieces of information: the name of the action, as well as the SAN, Tier and Lead Office.

Focus of the Executive Summary:

- **Rationale:** Why is the action needed? Is the action required by statute or courts? Who cares about this action?
- **Overall approach:** What environmental problem are we trying to solve? What is the range of tools and approaches that will be considered? Which ones will not be considered? Can we set performance goals to address the problem or support the use of innovative approaches?
- **Resource implications:** How significant are funding or staffing issues? Can tradeoffs between funding and product quality be quantified (e.g., what options exist for additional levels of data collection, more detailed modeling of a certain type, etc., and the implications of those extra efforts)?
- **Other management-level issues:** Potential legal or policy issues, timing constraints, major scientific uncertainty, controversy, or information quality limitations, economic implications, enforceability of rule, likely stakeholder concerns, substantial efforts needed related to regulatory analysis requirements such as small business impacts, etc.

Preliminary v. Detailed Blueprint

The executive summary in the Detailed Blueprint should build from the one in the Preliminary Blueprint. In the Detailed Blueprint, the executive summary should make explicit the key decisions in how analysis will be conducted, in order to seek final agreement on those decisions. The Detailed executive summary should also alert management to any new issues that have arisen since the Preliminary Blueprint.

B. Introduction

The introduction should be brief, provide sufficient background, and establish the proper context for the action. The following three areas should be included:

[13]See EPA Action Development Process Guidance (http://intranet.epa.gov/adplibrary).

1. **Summary of important points:**
   - Why is this action needed? What is the environmental or public health problem that must be addressed?
   - Any statutory or court-ordered deadlines
   - Brief summary of the action and any necessary background
     - prior events, related rules/actions, complicating factors
     - why certain legal, economic, or scientific issues may be important to this action

2. **Extent of Agency discretion:**
   - Is the action overall legally mandated (e.g., by statute) or discretionary?
   - What *aspects* of the action would be discretionary, (i.e., where does EPA have flexibility to make decisions)? What is the potential range of regulatory/non-regulatory options?
   - What are the minimum requirements? Where is there flexibility

3. **Rationale for the action:**
   - To the extent that the action is discretionary, what are the key arguments for and against the action?
   - Present any preliminary statistics characterizing the magnitude of the environmental or health problems being addressed, or providing perspective relative to other actions.
   - If it is a rule, what is the market failure that the action would address? (e.g., environmental externality—costs to the environment that are not being paid for by those causing them, lack of information causing inefficient markets, very high transaction costs that prevent compensation or trading, monopoly).[14]

Preliminary v. Detailed Blueprint

The introduction that was used in the Preliminary Blueprint may require only modest changes for use in the Detailed Blueprint. The rationale for the action generally will not have changed between the Preliminary and Detailed Blueprints. The Detailed version of this section can expand upon the text in the Preliminary version to the extent that legal reasoning has evolved or new information has become available.

[14]See "EPA's Guidelines for Preparing Economic Analyses" (http://yosemite1.epa.gov/ee/epa/eed.nsf/pages/guidelines); OMB's guidelines on RIAs (http://www.whitehouse.gov/omb/inforeg/riaguide.html).

C. Types of Approaches

This section discusses what approaches will be seriously considered, analyzed, and ultimately compared in documents supporting the action. This can have a major impact on the quality of the final action, because failing to analyze a reasonable option can exclude a potentially superior alternative. It is important to consider various types of approaches for both regulatory actions and non-regulatory actions. For regulatory actions, possible voluntary or innovative options should be considered. For non-regulatory actions, such as guidance or reports to congress, alternative approaches might be the degree of specificity to include in the document or the degree to which existing materials or analysis may be used rather than original analysis. These are just examples to spur thought. The main point here is that workgroups should reflect on alternative approaches to solving the issue at hand, thereby helping to ensure that appropriate information will be available for decision makers.

This part of the Blueprint answers the following questions:

Type of Action: Describe the types of regulatory and non-regulatory approaches (types of mechanisms) that will be evaluated. Are educational, voluntary, incentive-based, market-based, or other innovative approaches being considered and if so, how? If not, why not? Will performance-based, technology-based, or other pollution prevention approaches be analyzed? If not, why not? EPA's policy is to consider a wide range of innovative approaches and to promote analysis that may reveal effective new solutions. The appropriateness of innovative approaches needs to be decided on an action-by-action basis but a variety should be considered, including:

- Market-based incentives that cost-effectively achieve and/or exceed other traditional compliance strategies.
- "Performance-based" standards that allow entities to choose how best to reach a mandated goal.
- Actions that focus on characteristics of a particular sector to promote understanding and implementation.
- Other incentives that encourage performance beyond basic compliance .

Even for non-regulatory actions, it may be appropriate to consider alternative approaches in a Blueprint. For example, alternative approaches discussed in a non-regulatory action might be a choice between developing a new document with new analyses and drafting a short summary document that essentially compiles existing documents.

Scope of Action: This section of the Blueprint should provide a very brief summary of the industry or affected entities to provide perspective on the magnitude of the environmental problems and also the potential complexity of analysis and action.

- What entities could be targeted? How many facilities and in what locations?
- Is the diversity of the entities affected by the action an issue?

- Describe the types of targeting or sub-categorization in scope of the action that will be considered. Will the office look into the possibility of creating subgroups to treat differently? Different geographic areas? Segregate by size of business? Other types of subcategories?
- How might various approaches affect the expected benefits?
- If data are not adequate to address these issues, identify what data are needed and the process and date by which they will be gathered and analyzed.
- For non-regulatory options, it may be appropriate to consider the merits of both a broad or narrow approach.

Preliminary v. Detailed Blueprint

Following up on the Preliminary Blueprint's discussion of broad types of options (e.g., incentives vs. absolute standards), the Detailed Blueprint should list specific approaches or even particular regulatory and non-regulatory options that have been chosen for further analysis. In the Detailed version, the following questions should be addressed in a listing of the regulatory or non-regulatory options or approaches to be analyzed:

- How many options are expected to be presented in the supporting analysis (e.g., Regulatory Impact Analysis (RIA))[15] and included in summary tables showing costs and benefits?
- What will those options include (e.g., is the plan to compare 2-3 different levels of stringency)?
- Will some options be investigated and screened in some way but not included in the full economic or risk analysis? What kinds of options will not be fully analyzed and why?
- Is there any controversy (e.g., among stakeholders) over which options are chosen for analysis?
- Will all options be analyzed with and without a certain additional provision(s)?
- Will more than one possible compliance date be analyzed?

D. Analysis and Outreach

The following pages provide guidance on completing information related to six key analytic and outreach topics. The first five topics represent major types of analysis that support EPA actions. The sixth topic ("Other Key Topics") is included to acknowledge the variety of Agency activities. For some actions, important information may not fall neatly into one of the other categories.

[15] See "NCEE's Guidelines for Preparing Economic Analyses" (http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html); OMB's Circular A-4 (http://www.whitehouse.gov/omb/circulars/a004/a-4.html).

The Detailed Blueprint (and to a lesser extent the Preliminary Blueprint) should present a plan for addressing each key topic. For example, it should include a summary of the plans for: public participation; how each outstanding scientific issue will be handled; how the Regulatory Impact Analysis will be conducted under EO 12866[16]; and so on. The plans, generally speaking, should summarize what will be done, by whom, and by when, and should highlight the implications of key decisions. For example:

Key Topics for Analysis and Outreach:

1. Scientific Analysis
2. Economic Analysis
3. Stakeholder Involvement
4. Legal Issues
5. Implementation, Enforcement, and Compliance Assurance
6. Other Key Topics

- *What* decisions and activities are on the critical path (i.e., What needs to be done next? What determinations must be made, panels formed, analyses conducted, etc.?)? If decisions have been made, what are they (e.g. how will the analyses be conducted?)?
- *Who* will take the lead on each topic and what are their next steps? How will the workgroup determine how relevant or important this topic is for this action (e.g., does the workgroup need to assess impacts on small entities?)?
- *When* will these steps take place (Preliminary timeline)? Is the schedule realistic?
- *What* are the resource implications? Is this action likely to require substantial funding, staff resources, or lead time to ensure high-quality data, science, and analysis? Is there any sense of magnitudes of those requirements relative to other actions (at least whether large, moderate, small)?[17]

Guidance is provided below for each of the key topics, from science to enforcement. Appendices provide more detailed questions or issues that may be appropriate to consider and include in a Blueprint for several sections. Most Blueprints are expected to address the questions and issues presented in this guidance. However, specific questions or issues provided may not be relevant for a particular action. Similarly, there may be important questions that should be addressed in a Blueprint but are not listed here.

The Regulatory Development Library intranet site contains text, guidance, and templates for a wide range of Statutes, Executive Orders (EOs), policies, and other requirements. It should be carefully consulted before an Analytic Blueprint is drafted.[18]

1. Scientific Analysis

This section of the Blueprint describes plans for collecting and analyzing data, and conducting scientific analyses and reviews that are needed to ensure that decisions are based on sound science. The quality of science and analysis that inform EPA decisions is vital to the

[16]See EPA's "Guidelines for Preparing Economic Analyses" (http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html); OMB's Circular A-4 (http://www.whitehouse.gov/omb/circulars/a004/a-4.html).

[17]For example, the Blueprint could state that a very high level of public involvement is expected for this action, or that small business analysis is unlikely to require significant resources in this case, or that an economic impact analysis is likely to require substantial contractor support.

[18]See http://intranet.epa.gov/adplibrary

credibility of those decisions and ultimately EPA's effectiveness in protecting human health and the environment. Scientific products are used to:

- Accurately scope and frame the boundaries of the problem,
- Identify feasible and innovative technologies and regulatory options,
- Establish standards for human health and ecological protection, quantify the costs and benefits of various options (through engineering analysis, risk analysis, human health or ecological assessment, and economic analysis), and
- Develop testing and monitoring approaches to assess compliance and measure environmental progress.

Key Topics for Analysis and Outreach:

1. *Scientific Analysis*
2. Economic Analysis
3. Stakeholder Involvement
4. Legal Issues
5. Implementation, Enforcement, and Compliance Assurance
6. Other Key Topics

There are many ways to approach an analytical problem and what follows is a simple logical construct to assist you. First is a list of general areas of scientific inquiry to consider in the context of your action. After you have identified the areas that deserve further work, you are asked to follow a systematic approach to address each one. Finally, a list of more specific questions is provided in Appendix 1 to help guide your thinking as you prepare this section of your Blueprint.

Areas of Scientific Analysis

There are a number of key scientific questions that the workgroup should address when developing this portion of the Blueprint, e.g.:

- Has the environmental or public health problem been adequately characterized or do we need additional information to fully scope the problem? What additional information do we need?
- What information is needed to adequately characterize the regulated entities?
- What data and scientific analyses are needed to support the decision (e.g., monitoring needs, modeling tools)?
- What are the known science issues that are pertinent to this action? Is there a lack of agreement within the scientific community about any of the science issues? What additional data are needed to reduce scientific uncertainties?
- Will a decision be made on the basis of a risk assessment? If so, what type of information will be needed to complete this risk assessment?
- What types of risk management options are likely? What information is needed to evaluate the risk management options and to measure the environmental or public health outcomes?
- Has a high quality literature search been conducted?

Workplan

In considering each question, the workgroup should develop a list of the data and scientific analyses that are needed to support this action. For each type of data and scientific information identified as needed to support the action development, the workgroup should address the following overarching elements in the scientific plan section of the Blueprint:

1. **Data Gathering:** Set forth plans for gathering the needed scientific information (schedule, sources, and roles). Also describe plans to ensure that the information used in the decision meets the Agency's Information Quality Guidelines and Peer Review Policy.
2. **Analysis:** Describe plans for analysis, identifying key assumptions and tradeoffs between further analysis and resources or timing.

Specific questions to consider when outlining a scientific work plan include:

- Schedule and Resources: What is the schedule for obtaining and analyzing the information, what resources will be required, and who is responsible? Note that the schedule should include the time necessary to obtain OMB approval of any ICRs that may be needed to collect data.
- Quality Assurance: What quality assurance measures (e.g., Quality Assurance Project Plans) will be addressed in gathering and analyzing the data? Will these plans ensure that the information used in the decision meets the Agency's Information Quality Guidelines?[19]
- Scientific Expertise: What types of scientific expertise would be helpful in obtaining and analyzing this information? Who are the recognized experts, both within and outside the Agency? How can EPA access these experts?
- Risk Characterization: Consistent with Agency guidance and policies, explain significant uncertainties and how they will be communicated in the presentation of results.[20]
- Peer Review: What are the plans for peer review? What type of peer review is needed (e.g., internal, external, or review by the Science Advisory Board or other FACA committee)? Will these plans satisfy the Agency's Peer Review Policy?[21]

Preliminary v. Detailed Blueprint

The Preliminary Blueprint should reflect as complete a draft scientific plan as is possible within the time allotted. At a minimum, the workgroup should identify the key scientific uncertainties and areas of controversy that are known, the data and studies that are already available, and a rough idea of the types of additional analyses or assessments that are needed. The workgroup should identify any issues that are known concerning resources and the schedule and should identify potential solutions and options for management to consider when providing early guidance.

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[19]See "2002 Information Quality Guidelines" (http://www.epa.gov/quality/informationguidelines)

[20]See Risk Characterization Program and "Rick Characterization Handbook" (http://www.epa.gov/osp/spc/2riskchr.htm).

[21]See "Peer Review Handbook - 2nd Edition" (http://www.epa.gov/osp/spc/2peerrev.htm); and "Peer Review in the Rulemaking Process Fact Sheet" (http://intranet.epa.gov/adplibrary)

Building on the structural outline in the Preliminary Blueprint, the workgroup's next step is to develop a detailed plan and schedule for obtaining the data, conducting scientific analyses, and addressing new issues (any that have been identified since the Preliminary Blueprint). This plan should identify the information needed, the schedule for producing it and getting it peer reviewed, the resources needed, and the office responsible for the various steps.

2. Economic Analysis

This section of the Blueprint should present plans for data collection, analysis, and presentation related to economic analysis supporting the action. Significant tradeoffs between analysis and resources or timing should be highlighted. EPA's National Center for Environmental Economics published "Guidelines for Preparing Economic Analyses," which will be a useful resource for the workgroup as it plans its analyses[22]. For specific questions or guidance, you may want to consult with the workgroup representative from the Office of Policy, Economics and Innovation.

Key Topics for Analysis and Outreach:

1. Scientific Analysis
2. ***Economic Analysis***
3. Stakeholder Involvement
4. Legal Issues
5. Implementation, Enforcement, and Compliance Assurance
6. Other Key Topics

There are many ways to approach an analytical problem and what follows is a simple logical construct to assist you. First is a list of general areas of economic inquiry to consider in the context of your action. After you have identified the areas that deserve further work, you are asked to follow a systematic approach to address each one. Finally, a list of more specific questions is provided in Appendix 2 to help guide your thinking as you prepare this section of your Blueprint.

Areas of Economic Analysis

In many EPA actions, there are several areas of analysis that could be informed by economics. The list of analytic areas below should be useful in organizing the Blueprint's discussion of economic issues.

Areas of analysis related to economics:

1. Characterization of the industry and the environmental/health problem
2. Costs of options (social costs, discounting, no-action scenarios, etc.)
3. Benefits of options (monetization, distributional effects, sensitive subpopulations, valuation of health/mortality impacts on children, latency, ecological benefits, etc.)
4. Cross-media impacts

[22]See "Guidelines for Preparing Economic Analyses." (http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html)

5. Results and Option Selection (presentation of policy alternatives, incremental effects, etc.)
6. Other analyses involving economics

For any relevant areas of analysis, the Blueprint should address the following topics:

1. **Data Gathering Plan:** Identify the information needed and plans for gathering information (schedule, sources, roles). Also describe plans to ensure that the information used in the decision meets the Agency's Information Quality Guidelines[23] and Peer Review Policy.[24]
2. **Analysis Plans:** Describe plans for analysis, including key assumptions and tradeoffs between quality analysis and resources or timing.

In discussing data and analysis plans, the Blueprint should summarize resource and timing issues to the extent they hinder the use of the best possible data for the economic analysis. This might include availability of staff or outside experts, cost of additional data collection, need for peer review, need for results from research underway, and so on.

NOTE: Detailed lists of questions expanding on the above areas may be found in Appendix 2, and should be consulted in preparation of the Blueprint.

When outlining an economic work plan:

- Schedule and Resources: What is the schedule for obtaining and analyzing the information, what resources will be required, and who is responsible? Note that the schedule should include the time necessary to obtain OMB approval of any ICRs that may be needed to collect data.
- Quality Assurance: What quality assurance measures (e.g., Quality Assurance Project Plans) will be addressed in gathering and analyzing the data? Will these plans ensure that the information used in the decision meets the Agency's Information Quality Guidelines?[25]
- Economic Expertise: What types of economic expertise would be helpful in obtaining and analyzing this information? Who are the recognized experts, both within and outside the Agency? How can EPA access these experts?
- Risk Characterization: Consistent with Agency guidance and policies, explain significant uncertainties and how they will be communicated in the presentation of results.[26]
- Peer Review: What are the plans for peer review? What type of peer review is needed (e.g., internal, external, review by a FACA committee)? Will these plans satisfy the Agency's Peer Review Policy?[27]

[23]See "2002 Information Quality Guidelines" (http://www.epa.gov/quality/informationguidelines)

[24]See "Peer Review Handbook—2nd Edition" (http://www.epa.gov/osp/spc/2peerrev.htm); and "Peer Review in the Rulemaking Process Fact Sheet" (http://intranet.epa.gov/adplibrary).

Preliminary v. Detailed Blueprint

The Preliminary Blueprint should reflect as complete of a draft economic plan as is possible within the time allotted. At a minimum, the workgroup should identify the key economic uncertainties and areas of controversy that are known, the data and studies that are already available, and a rough idea of the types of additional analyses or assessments that are needed. The workgroup should identify any issues that are known concerning resources and the schedule and should identify potential solutions and options for management to consider when providing early guidance.

Building on the structural outline in the Preliminary Blueprint, the workgroup's next step is to develop a detailed plan and schedule for obtaining the data, conducting economic analyses, and addressing new issues (any that have been identified since the Preliminary Blueprint). This plan should identify the information needed, the schedule for producing it and getting it peer reviewed, the resources needed, and the office responsible for the various steps.

3. Stakeholder Involvement

Stakeholders include affected parties as well as other partners (e.g., general public, regulated entities, environmental groups, state/local/tribal governments, other federal agencies or organizations, etc.).[28]

Stakeholder involvement is an important part of the information collection and assessment that supports action development. It can be helpful in several areas: characterizing an industry or problem, identifying and refining alternative regulatory and non-regulatory options, increasing transparency and compliance, checking practicality, describing costs or benefits of various options, and complying with various Statutes and Executive Orders (EOs) (E.O.'s) regarding rule-making.

Key Topics for Analysis and Outreach:

1. Scientific Analysis
2. Economic Analysis
3. ***Stakeholder Involvement***
4. Legal Issues
5. Implementation, Enforcement, and Compliance Assurance
6. Other Key Topics

Areas of Stakeholder Involvement and Analysis

The Blueprint should discuss plans for stakeholder involvement. This could include a combination of various types of consultative processes:

1. **Outreach:** Basic communication keeping outside parties informed of plans and actions.
2. **Information Exchange:** Stakeholders and EPA provide and exchange data, opinions, and options.

[28]See EPA's Public Involvement website at http://www.epa.gov/stakeholders.

3. **Recommendation:** Stakeholders provide non-binding, but influential advice or recommendations.
4. **Agreements:** Stakeholders and EPA reach practical agreement.

Each of these types of consultations should be considered as a means of soliciting input. Thought should be given to how consultation efforts for action development activities should be structured to meet relevant Statutes, Executive Orders (EOs) or policies such as: Regulatory Planning and Review[29]; Federalism[30]; Consultation and Coordination with Indian Tribal Governments[31]; Negotiated Rulemaking Act[32]; Regulatory Flexibility Act (RFA)/Small Business Regulatory Enforcement Fairness Act (SBREFA)[33]; Unfunded Mandates Reform Act (UMRA)[34]; Federal Advisory Committee Act (FACA)[35]; EPA's Public Involvement Policy[36]; and the EPA Small Business Strategy.[37] Some of these laws and E.O.'s have very specific requirements concerning consultations we must undertake, with whom, and at what point in the action development process. For an up-to-date list, and additional information and guidance on individual items (e.g., full text E.O.'s, guidance, and templates) please see the Action Development Process Library intranet site.[38]

Data Analysis to Support the Action:

The stakeholder involvement section of a Blueprint should:

- Identify the key players and affected groups.
- Describe plans for the type of public participation in order to provide information and effective outreach. You should include any plans of providing technical or financial assistance to the public to facilitate involvement.
- List anticipated dates for stakeholder involvement. It is important to start the planning early so stakeholders can be present at the meetings.
- Assess whether this action might trigger special treatment related to stakeholder involvement stemming from Statutes or Executive Orders (EOs).
- Identify time or resource constraints. Even when time or resource constraints are limiting, stakeholder involvement may be important in the context of particular Statutes, E.O.'s or Agency policy (e.g., UMRA).

Preliminary v. Detailed Blueprint

The Preliminary Blueprint should, at a minimum, list key stakeholders expected to be contacted during action development. Building on the Preliminary Blueprint, the Detailed Blueprint should highlight changes in the schedule and other key aspects of the plan.

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[29] See http://www.epa.gov/fedrgstr/eo/eo12866.htm.
[30] See http://www.epa.gov/fedrgstr/eo/eo13132.pdf.
[31] See http://www.epa.gov/indian/pdfs/13175.pdf.
[32] See http://www.epa.gov/ocrpage1/adraact.htm.
[33] See http://www.epa.gov/sbrefa/statute/rfasbrefa_act.pdf.
[34] See http://intranet.epa.gov/adplibrary
[35] See http://www.epa.gov/ocem/faca/index.htm.
[36] See http://www.epa.gov/publicinvolvement/policy.htm
[37] See http://www.epa.gov/sbo
[38] See http://intranet.epa.gov/adplibrary

The Detailed version of this section should expand on that of the Preliminary Blueprint, summarizing plans for stakeholder involvement and highlighting any important decisions about the extent of efforts to provide for involvement. The discussion should make clear whether stakeholder involvement has been and will be adequate, given the various regulatory analysis requirements covering consultation and EPA's policy on public involvement[39].

4. Legal Issues

This section of the Blueprint presents key legal issues relevant to the development of the particular action. In particular, it should present the need for data gathering or analysis, and the plans for addressing particular legal issues. For specific questions or guidance, you may want to consult with the workgroup representative from the Office of General Counsel.

Key Topics for Analysis and Outreach:

1. Scientific Analysis
2. Economic Analysis
3. Stakeholder Involvement
4. ***Legal Issues***
5. Implementation, Enforcement, and Compliance Assurance
6. Other Key Topics

Areas of Legal Analysis

Any precedent-setting, novel, or controversial legal issues should be highlighted in this section. The Office of General Counsel's workgroup representative will typically provide legal advice to the workgroup, and OGC's views should be reflected in this section.

The Legal Analysis section may discuss:

- What data and analyses are required under the law to support the action?
- Areas, to the extent known, where there may be significant discussion with the Office of General Counsel on topics such as:
  - any necessary legal research or decisions (include relevant consideration of questions or uncertainties),
  - rationale for regulation,
  - authority to regulate,
  - authority to use certain mechanisms or to target certain subcategories,
  - legal defensibility of all significant choices likely to be made (e.g., such as stringency of standards or choice not to regulate in certain areas), and
  - significant legal precedents or court cases.

[39]See http://www.epa.gov/publicinvolvement/policy.htm.

Preliminary v. Detailed Blueprint

There may be little difference between the Preliminary and Detailed versions of the Legal Issues sections. In the detailed version, any changes or additions to the Preliminary legal issues section should be explained and any plans for further work should be mentioned.

5. Implementation, Enforcement, and Compliance Assurance

This section of the Blueprint considers the data collection and analysis needs related to implementation, particularly enforcement and compliance assistance efforts. It may be helpful when working on this section of the Blueprint to look to the Office of Enforcement and Compliance Assurance's (OECA) workgroup representative, as well as OECA's public guidance documents available on the internet at: http://www.epa.gov/compliance.

Key Topics for Analysis and Outreach:

1. Scientific Analysis
2. Economic Analysis
3. Stakeholder Involvement
4. Legal Issues
5. ***Implementation, Enforcement, and Compliance Assurance***
6. Other Key Topics

Areas of Analysis

This section highlights analytic information related to potential implementation burden, compliance assistance tools, and potential enforcement strategies.

Implementation-related questions for Analytic Blueprints

- Who will implement the action (States, Tribes, Regions, etc.)? How? Adopt State, Tribal programs? Periodic monitoring? Mandatory reporting?
- Will an Information Collection Request (ICR) be necessary under the Paperwork Reduction Act (PRA) to authorize any monitoring, record keeping, or reporting requirements?
- Is there an opportunity for a creative implementation strategy that may be more effective/less burdensome?
- Does a compliance guide need to be developed per SBREFA?
- Will any type of targeted compliance assistance be appropriate?
- Are environmental justice issues associated with implementation a concern? If so, how are they being analyzed?
- Does a Small Government Agency Plan need to be developed per UMRA?
- How will the rule identify clear, measurable standards of conduct? Will it be possible, for both the source and the regulatory authority, to determine whether the regulated entity is in compliance? Will it be enforceable, with any monitoring issues adequately addressed, and with clear descriptions of violations and clear consequences?
- What is the burden associated with implementation, for both the regulated community and the regulators?
- To what extent might other compliance assistance tools be appropriate?

Preliminary v. Detailed Blueprint

The Preliminary Blueprint should highlight any particular implementation issues that need to be addressed. The Detailed version of this section should provide the data collection and detailed analysis to ensure implementation issues are evaluated and considered and highlight any changes in the schedule or other key aspects of the plan.

6. Other Key Topics

This optional section should capture any other important information that did not fit within one of the previous five topic areas. The Blueprint should discuss the information or analysis necessary and present plans for how it will be addressed.

Key Topics for Analysis and Outreach:

1. Scientific Analysis
2. Economic Analysis
3. Stakeholder Involvement
4. Legal Issues
5. Implementation, Enforcement, and Compliance Assurance
6. *Other Key Topics*

E. Workgroup Members and Contact Information

As an attachment to the Analytic Blueprint, include a list of workgroup members and their contact information. This may be printed from the RAPIDS database once that information is verified by the workgroup. If there are any changes, this section should be updated for the Detailed Blueprint. Make sure changes are updated in RAPIDS via your RSC representative.

F. Draft Schedule Information

The Preliminary Blueprint should include a Preliminary schedule as an attachment. At a minimum, process milestones (e.g., Option Selection) and external deadlines should be noted.

For the Detailed Blueprint, an updated schedule should be included as an attachment. Any significant or notable changes since the Preliminary Blueprint should be discussed. The schedule should note key events in the action development process, including (where relevant):

- Milestones for key reports or studies (e.g., dates that important data collection will be completed and peer reviewed, draft risk assessment will be available for workgroup initial review, etc.)
- Activities supporting action development, such as:
  - RFA/SBREFA Small Business Advocacy Review Panel
  - Public hearings or other significant stakeholder involvement
  - Consultation activities required for rulemakings by laws and E.O.s
  - Peer review activities
  - Establishing a public docket.

- Projected action development process milestones:
  - Frequency of workgroup meetings
  - Blueprint approval expected from senior management
  - Options Selection meeting
  - Final Agency Review
  - Submit to OMB for review
  - Send to Administrator for signature
  - NPRM publication in Federal Register
  - End of public comment period
  - Reconvening of Agency Workgroup
  - Early guidance from senior managers regarding public comments (if needed)
  - Final Agency Review
  - Submit to OMB for review
  - Send to Administrator for signature
  - FRM publication in Federal Register
  - Completion of compliance guide(s), if any

Resources and Timing

The schedule should be accompanied by a brief summary of resource and timing issues. In particular, the following should be addressed:

Resources:

- List general resources available as full-time equivalents (FTEs) or some other metric.
- Describe projected contract support (dollars, FTEs, or other metrics). This should be broken out by major task.
- Are there resource constraints?

Timing:

- Describe first steps and an approximate timeline to indicate what data gathering activities or analyses need to start immediately and roughly when this data would become available.
- Is there a critical path (i.e., sequencing issues or constraints)?
- Is the timing of particular data gathering efforts likely to be of concern?
- Are other offices working on a relevant portion of the effort?

III. How Does the Blueprint Approval Process Work?

This chapter sets out the process and timeframes for completing the Preliminary and Detailed Blueprints, provides a flowchart illustrating a sample timeline to help workgroups manage the Blueprint process, and describes how Blueprint development is tracked.

A. Overview

Contents of this Chapter

The development process is essentially the same for both the Preliminary (P-ABP) and the Detailed (D-ABP) Blueprint. Each stage provides 60-days during which the workgroup discusses, drafts, revises, and agrees upon the Blueprint. Each stage also includes a step allowing for senior managers to engage in this inter-office dialogue regarding the analyses that will support the action. These steps are meant to ensure that managers have opportunities to affect policies and planning, rather than only being involved when disputes arise in the workgroup, or at the tail end of the action development process. It is also important to note that your office may have adopted additional procedures for the P-ABP and/or D-ABP development process. This guidance describes the general Agency process, but you will also need to identify any applicable procedures within your office. To do so, consult your Regulatory Steering Committee representative or Regional Regulatory Contact.

The approval process differs between the two Blueprint phases; calling for early guidance from senior management to discuss the P-ABP and formal management sign-off on the D-ABP.

P-ABP: There is no formal "approval" step for the P-ABP. However, the workgroup members should agree that it is ready to be circulated for early guidance purposes. If the workgroup

cannot reach complete agreement, the lead office can choose to move forward to seek early guidance. The workgroup should identify possible areas of disagreement and highlight these remaining issues to senior management. Early guidance is an opportunity for senior management to engage and for the workgroup to obtain input regarding analytical or policy direction that should be reflected in the D-ABP. When giving early guidance, the lead office should consider other policy issues and priorities of other AAs/RAs. The lead office should also provide participating AAs/RAs with meaningful opportunities to contribute to early guidance decisions and should obtain agreement from participating offices on issues that affect them. The recommended way to accomplish this is to have an early guidance meeting involving all of the participating offices to discuss significant issues and to mutually agree on the priorities and general direction for the action. This cross-office management meeting should be accomplished within 30 days of workgroup agreement on the P-ABP, by which time each of the workgroup representatives will have met with their managers and prepared them to contribute substantively to an early guidance meeting. (See detailed P-ABP process description below.)

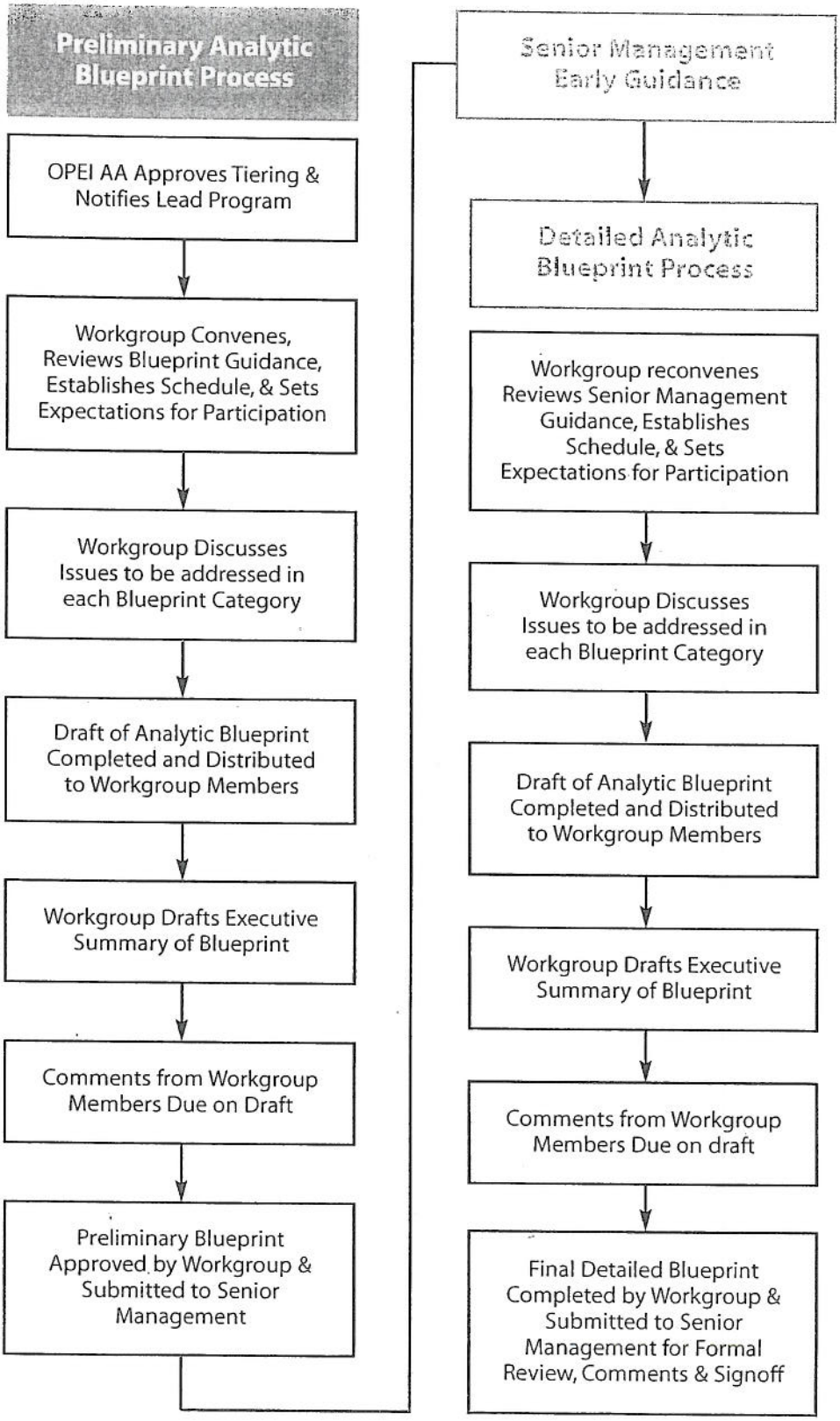
D-ABP: Formal agreement on the D-ABP is important because it commits all participants to the proposed approach and delineates their responsibilities. In this step, the participating offices on the workgroup provide an official position from their top management and either formally concur or concur with comment on the D-ABP. Formal cross-Agency review may be completed by having each participating office document its position in a memorandum. Based on the responses, a cross-Agency meeting may be scheduled. (See detailed D-ABP process description below.)

Figure 1, on the next page, is a sample timeline to help workgroups manage development of Analytic Blueprints. **It is intended simply as a guide to facilitate the planning process for the workgroup. The specific timeline for Blueprint development may vary, but the entire workgroup process is expected to be completed within no more than 150 days of tiering approval**[40]. Tiering approval is the date when the OPEI's Associate Administrator (AA) formally approves the tiering designation recommended by the RSC.

If more time is necessary to complete either the P-ABP or D-ABP, the lead office should alert the RSC that additional time is needed to develop the Blueprint. The RSC will discuss the relevant issues (e.g., impending deadlines and impact of schedule slippage on compliance with the ADP) and consider ways to help the workgroup stay on a reasonable schedule.

[40]It might be easier to think of it either as 5 months (i.e., 2 months for P-ABP, 1 month for Early Guidance, and 2 months for D-ABP), or 20 weeks (i.e., 8 weeks for P-ABP, 4 weeks for Early Guidance, and 8 weeks for D-ABP).

B. Figure 1: Sample ABP Process Flowchart



C. Timing and Steps of the Drafting and Approval Process

Preliminary ABP

Process Steps

1. Lead office convenes Workgroup as soon as possible after action is tiered. Ideally, this would be within two weeks of tiering approval. (To get a running start, the Workgroup can also be convened informally after offices have assigned staff, but before OPEI's AA has signed off on the tiering form.)

2. Workgroup reviews Analytic Blueprint Guidance, agrees on roles and responsibilities for participation, and establishes a schedule for developing the P-ABP. Workgroup chair from the lead office establishes a target completion date and informs its RSC representative.

3. Workgroup members collaborate to write the Blueprint outline and discuss issues/options to be addressed in each section of the Blueprint.

4. All workgroup members contribute to the preparation of the P-ABP. While the lead office may prepare a first draft, Blueprint creation is expected to be a team effort involving all interested offices and providing a clear understanding among workgroup members about what information will be collected and analyzed.

5. Workgroup members submit timely constructive comments to the lead office and the lead office prepares the final draft.

6. Workgroup agrees upon the final P-ABP. If the workgroup cannot reach complete agreement, the lead office can choose to move forward and raise any remaining issues raised to senior management. Workgroup chair from the lead office distributes copies to workgroup and submits the final P-ABP to its RSC representative.

7. The RSC representative will submit the final P-ABP to the AA, who is expected to provide early guidance within 30 days. The lead office should provide meaningful opportunities for senior management from each participating office/Region represented on the workgroup to contribute to early guidance and should obtain their agreement on issues that affect them.

8. The recommended way to accomplish early guidance is to have an early guidance meeting, scheduled by the lead office, involving all of the participating offices. Invited senior managers may delegate attendance, but the person who participates must be able to *represent* the office, not simply attend on their behalf. The RSC representative should help coordinate the scheduling of any early guidance meeting and ensure that copies of the final P-ABP are distributed to senior management.

9. Early guidance always comes from senior management, although the level of management differs for Tier 1 and Tier 2 actions. If the guidance isn't given directly to the workgroup, the lead AA/RA is responsible for assuring that it is communicated to them.

   - Tier 1 Actions: The Administrator or Deputy Administrator provides early guidance, with input from participating AAs/RAs from across the Agency.
   - Tier 2 actions: The lead AA/RA gives early guidance to the workgroup, with input from the participating AAs/RAs. The lead AA/RA should consider the policy issues and priorities of other AAs/RAs when giving early guidance

Process Notes

- The P-ABP should focus on compiling early information and facilitate obtaining early management guidance.
- Issues that cannot be resolved at the staff level should be quickly elevated to management for a decision and reported back to the workgroup.
- Workgroup members should inform their senior management about the content of the P-ABP in preparation for early guidance. The workgroup should agree that the P-ABP is ready to be presented to senior management. If the workgroup cannot reach complete agreement, the lead office can choose to move forward and raise any remaining issues to senior management.
- The 30-day period between submitting the P-ABP to senior management and initiating work on the D-ABP is **not "down time"**. To the contrary, each workgroup member is expected to use this time to brief their senior management in preparation for early guidance and to work with the lead office to resolve any outstanding issues before the Workgroup reconvenes to initiate work on the D-ABP.
- The lead office should document decisions made in early guidance and distribute it to all workgroup members.

Detailed ABP

Process Steps

1. As soon as possible following completion of the P-ABP and the early guidance meeting, the lead office reconvenes the workgroup to discuss the senior management input and develop the D-ABP (goal is 30 days or less to reconvene).
2. Workgroup agrees on roles and responsibilities for participation, establishes a schedule for the D-ABP, and the workgroup chair informs their RSC representative of the target date.
3. Workgroup discusses issues/options and collaborates on drafting the D-ABP. While the lead office may prepare a first draft, Blueprint creation is meant to be a team effort involving all interested offices and providing a clear understanding among workgroup members about what information will be collected and analyzed.

4. The draft D-ABP, when completed, is distributed to Workgroup by the lead office.
5. Workgroup submits timely constructive comments to the lead office and the lead office prepares the final draft.
6. When the final draft D-ABP is complete, the lead office should seek formal cross-Agency review. The workgroup chair should not assume agreement, rather should confirm with Workgroup that the final draft D-ABP is complete (an acknowledgment that there are no outstanding staff level issues). At this point, the workgroup chair asks their RSC representative to initiate the formal cross-Agency review process.
7. To begin the formal review process, the lead RSC representative and workgroup chair prepare a memo to the RSC representatives of the offices participating on the workgroup (with courtesy copies to the workgroup members) announcing the formal review, distributing the final draft D-ABP, and requesting an official position from each offices' top management. The timing of the memo will allow a full 15 working-day review. There could be times when a fifteen-day review isn't possible and a request for an expedited review is necessary. The lead office has the option to request an expedited review in a manner similar to that provided for Final Agency Reviews.
8. The memo from the lead office to participating office RSC representatives announcing the formal review should advise them that one person will be asked to respond on behalf of their office and that person is expected to represent the position of their AA/RA. Accordingly, even if an office is represented by more than one workgroup member, just one person will be asked to speak on behalf of their AA. It is the responsibility of the representatives of that office to coordinate with their senior management.
9. The announcement memo will advise the addressees that they can respond in one of two ways at the AA/RA level:
   - "**Concur**" should be used to show full agreement, although the reviewing office may provide editorial suggestions;
   - "**Concur with comment**" indicates the reviewing office has dissenting opinions, substantive comments or conditions which it wants the lead office to accommodate or elevate.
10. The lead office should receive a position memo from all participating offices immediately following the fifteen working-day review and proceed as follows:
    - If the lead office receives AA/RA "Concurrence" (no identified substantive concerns) from all participating responding offices, the lead office may provide the final draft D-ABP to the appropriate official for approval.
    - If the lead office receives an AA/RA "Concur with comment" identifying a substantive concern, the lead office should work with the commenting office and any other offices that may be impacted, to address the issue(s) before forwarding the final draft D-ABP to the approving official. If the lead office is not able to accommodate the reviewing

office, the workgroup chair should consult with their RSC representative to schedule a cross-Agency issues meeting. This cross-Agency meeting is intended to provide a courtesy face-to-face opportunity to discuss and potentially resolve the substantive issues identified in the AA/RA position memo. The representative of the commenting office is expected to represent the position of their AA/RA during the meeting; therefore it is the responsibility of the representative of that office to coordinate with their senior management. The lead office may request that RMD schedule:

- a cross-Agency meeting that is coordinated, chaired, and documented by RMD; or
- an issue presentation during a Regulatory Steering Committee meeting.

After this meeting, the lead office may decide to proceed to the approval stage without resolving the issue. The decision to proceed, along with a justification, should be documented in a memorandum to all participating offices. This memorandum will accompany the D-ABP when submitted for approval. The position memo from the dissenting office will also accompany the D-ABP when submitted for approval.

11. Obtaining approval upon completion of the D-ABP formal cross-Agency review process:

    - After obtaining formal review, the completed Blueprint and any written comments will be submitted by the lead office, to the appropriate official for approval. For Tier 1 actions, the Administrator or Deputy Administrator is the approving official. Tier 2 actions, the lead AA/RA is the approving official (although the Administrator or Deputy Administrator may want to be informed or briefed prior to final decisions).
    - Based on the formal cross-Agency review responses, it may be appropriate for a formal approval meeting to be scheduled with the approving official. Such a meeting should always be scheduled when it is requested by a participant, or if the responses indicate a disagreement in the approach taken in the D-ABP. The D-ABP, along with the formal cross-Agency review responses from the participating offices, should be submitted to the approving official, with copies to the appropriate managers of the participating offices, prior to such a meeting. The lead office and the commenting office(s) are encouraged to continue working together at the staff level during the time leading up to an approval meeting to resolve the remaining issue(s). If a resolution is achieved prior to the scheduled meeting, the approval meeting may be cancelled.

12. Finally, the lead office distributes the final approved D-ABP to the workgroup.

    - The workgroup may modify the approved D-ABP, in consultation with management, if the workgroup encounters situations where a change to the planned approach set out in the blueprint is appropriate. Quickly bring deviations from the D-ABP to the attention of the workgroup members and document substantial deviations. The workgroup chair will work with the workgroup member(s) to resolve any concerns and elevate any outstanding issues to management for decision.

Process Notes

- Ideally, the workgroup reconvenes no later than 30 days after the P-ABP was disseminated to obtain senior management early guidance.
- Issues that cannot be resolved at the staff level should be quickly elevated to management for a decision and reported back to the workgroup.

D. Tracking and Reporting Analytic Blueprint Efforts

Analytic Blueprints are a critical part of the Agency's Action Development Process. Accordingly, OPEI oversees Blueprint development. During the ABP development process, several dates are recorded in RAPIDS by the lead office RSC representative. These data comprise the substance of the report, in particular:

1. Projected P-ABP completion date (calculated - 60 days from OPEI AA tiering approval).
2. Actual P-ABP completion date (when lead office disseminates workgroup-approved document to each workgroup member in preparation for the early guidance meeting).
3. Projected Workgroup reconvening date (calculated - initially 90 days from tiering approval, but adjusted based on item 2, above).
4. Actual Workgroup reconvening date following early guidance meeting.
5. Projected D-ABP completion date (calculated - initially 150 days from tiering approval, but adjusted based on items 2 and 3, above).
6. Workgroup D-ABP completion (when workgroup completes document and submits for formal management review and sign-off).
7. Final approval of D-ABP (signature date of approving senior manager).

Just as Analytic Blueprints are a vital part of the Action Development Process, the Blueprint report is a crucial management tool for ensuring the development of quality actions. The report is the means by which the Agency can ensure that it realizes all of the *What Makes an Analytic Blueprint Effective* (see I.C., above).

IV. Where Can I Get Additional Information or References?

Additional information may be helpful in developing an Analytic Blueprint. The best place to find the information you need is the Agency's Regulatory Development Intranet site: (http://intranet.epa.gov/adplibrary).

This site is where guidance documents relevant to action development are maintained. This site includes information on Agency policies such as the *Action Development Process* and the *Public Involvement Policy*, as well as guidance on specific Statutory and Executive Order assessments. The site also tries to provide links to additional analytic guidance and policy documents that may facilitate development of Analytic Blueprints.

Your office may also have program specific procedures that apply to the development of your Analytic Blueprint. Do not forget to check with your Regulatory Steering Committee representative or Regional Regulatory Contact to find out what those might be. In addition to written reference material, the intranet site provides a list of people who might be helpful to you. Probably, the most useful contact for you is the Regulatory Steering Committee representative for your office. The RSC comprises a standing group of representatives from Assistant and Associate Administrators, Regions, and the Office of General Counsel (OGC). The RSC is responsible for primary oversight of the development of actions within its members' offices. The RSC is responsible for:

- Overseeing the action development process.
- Implementing the tiering process.
- Developing guidance to implement the action development process.
- Ensuring that rules comply with applicable statutes and EO directions.
- Ensuring that significant cross-program process issues are resolved or elevated to upper management.
- Advising the Regulatory Policy Council on issues related to action development.

Finally, if you still have questions you may want to contact the Regulatory Management Division. This group is entrusted with working with the Regulatory Steering Committee to manage the EPA's *Action Development Process*. Staff may be contacted through the intranet site as well.

Appendix 1—Science Section of Blueprint: Detailed Questions to Address

This list provides a convenient way to break up the discussion of scientific issues into separate topics. It makes clear that science can inform several different aspects of the analysis supporting an action. Science encompasses topics beyond just biology and chemistry. For example, scientific research can inform a risk assessment, but it can also shed light on what policy options have been successful in other countries, or what technologies will be feasible in coming years.

A. Areas of Scientific Analysis

1. Characterization of the Environmental or Public Health Problem Being Addressed

- What are the health and environmental risks?
- What additional information is needed to characterize the environmental or public health problem? How should this information be obtained?.
  - What is the magnitude of the problem?
  - Will this regulation disproportionately affect children, the elderly, or other sensitive populations?
  - Will this action disproportionately impact endangered/threatened species or critical ecosystems?
  - Where is the problem occurring geographically? When does it occur?
  - What are the direct sources and behaviors causing the problem? What are the important details related to the sources?

2. Characterization of the Regulated Entities

- What additional information is needed to characterize the regulated entities (e.g., emissions data, disposal practices, location, contaminant levels, and current risk management practices)?
- What are the source reduction, recycling, and treatment approaches being employed by the industry?

3. **Known Science Issues and Uncertainties**

- How sufficient or advanced is the state-of-the-science in this area?
- What are the known science issues? Is there disagreement within the scientific community on these issues? How should these disagreements be addressed?
- What are the scientific uncertainties in the data and/or tools that will be used? What can be done to reduce these uncertainties?
- What are the important assumptions being made in the analysis? Why are these assumptions being made? Is there strong scientific rationale for each of these assumptions? Is there general agreement within the scientific community on the major assumptions or theories used?
- How adequate are the research results, data, and analyses?
- What additional data or studies are needed to reduce the level of uncertainty and to obtain more widespread agreement on major assumptions?

4. **Data and Scientific Analyses Need to Support the Decision**

- What data are already available to support the decision? Are there gaps in the data? How should these gaps be filled? What additional data should be collected?
- Are models needed to support the action? Do these models exist or do they need to be developed? Have existing models been evaluated for their application to this decision?
- What studies are available to support the decision? What studies are being conducted and will they be completed in time? What studies need to be initiated?
- Do analytical tools need to be developed to support the action? Will they be developed on time? Have existing analytical tools been appropriately validated?

5. **Risk Assessment**

- What type of planning and scoping will be required for the assessment?
  - Will a hazard or risk assessment be needed?
  - Does EPA have sufficient information to perform an assessment of sufficient quality to match the needs of this decision? If not, what information is needed and how will it be obtained?
  - Some key areas where scientific data are critical:
    - Hazard identification
    - Emissions estimation
    - Dispersion/ fate and transport modeling and formation/decay chemistry

- Exposure assessment
- Ecological risk assessment
- Children's health analysis[41]

6. **Analysis of risk management options.**

   - What risk management options may be considered? What information is needed to evaluate these options and to measure the public health or environmental outcome?

7. **Literature search.**

   - Has a high quality literature search been conducted to identify key studies that relate to the decision? Is it recent?

B. Workplan

For each relevant area of analysis, the Blueprint should address data gathering and analysis that are needed to support the action and include a detailed work plan that lays out the schedule, the resources required, and the responsible party.

1. **Schedule/Resources**

- Identify the schedule/timeline, data sources, and parties responsible for obtaining the information needed and for analyzing it.
- Is an ICR needed? What are the plans and schedule for developing the ICR and obtaining OMB approval?
- Are there any significant tradeoffs between obtaining a quality analysis and resources or timing? Will the quality of underlying science be affected by other constraints? If so, this should be discussed, with an identification of any options for mitigating these impacts.

2. **Quality Assurance**

- What are the plans and schedule for meeting the Information Quality Guidelines?
- Does a Quality Assurance Project Plan need to be developed?

3. **Scientific Expertise**

- What type of scientific expertise is needed? Is this expertise available in house? If not, how can we access the expertise?
- Who are the recognized experts and will their judgments be elicited?

[41]See "Policy on Evaluating Risks to Children" (http://www.epa.gov/osp/spc/2poleval.htm).

- Has peer input been considered?

4. **Peer Review**

- What are the plans for meeting the Agency's Peer Review Policy for peer review of scientific and technical products?
- What type of peer review is needed (internal, external, SAB)? Include a schedule for the review and identify the resources that will be needed

5. **Risk Characterization**

- If a decision will be based on a risk assessment, how will potential risks be characterized and communicated? Are there sufficient data to ensure this level of communication?
- What are the plans for following the Risk Characterization Policy, as described in the Risk Characterization Handbook?

Appendix 2—Economics Section of Blueprint: Detailed Questions to Address

The list of analytic areas below should be useful in organizing the Blueprint's discussion of economic issues. For each applicable area of analysis, the Blueprint would answer the questions in the section immediately following this list.

A. Areas of Economic Analysis

1. Characterization of the Industry and the Environmental or Health Problem Being Addressed

The emphasis here is understanding the economic context to estimate the cost and benefit of potential options.

- What are the root economic causes driving the environmental problem?
- What categories or subcategories will be used to provide detailed economic analysis?
- What impacts will be estimated by subcategory of source type?
- At what level of aggregation will data and analysis be conducted (e.g., NAICS)?
- Will there be a breakdown by firm size? By firm? By region?
- How will distributional impacts be described? What groups will be compared?

2. Costs of Options

- The cost category should include not only engineering costs, but also full social costs, impacts on economy, prices, etc.
- Discount rate: What discount rates will be used in various steps of the analysis? (e.g., discounting costs, discounting economic benefits, discounting tonnage reductions, adjusting a value of a statistical life estimate to account for lag between exposure and health impacts, etc.?) Which rate will be used for primary estimates, or will alternative rates be used in parallel?
- What methods will be used to define baseline and projected no-action scenario?
- What are the anticipated impacts on prices and quantities of sales, and on price elasticities of demand and/or supply?

- What is the cost effectiveness, where applicable? (For example, in terms of estimated emissions reductions, lower pollutant concentrations, or reductions in risk?
- Compliance Costs
  - How will the components of compliance and enforcement costs be estimated and projected?
  - What sampling approach will be used to collect data on compliance costs?
  - Will model facilities be developed, and if so, how?
  - Will "learning curves" be assumed to reduce future costs, and if so, how?
  - Will changes in consumer and producer surplus be quantified, or will just engineering costs be estimated assuming quantities sold do not change?
  - How will other costs be estimated?

3. Benefits of Options

- How will benefits of various avoided adverse health effects be quantified in monetary terms? How will benefits of various subpopulations (e.g., children) be addressed?
- Has benefit transfer been considered?
- Will latency be considered when assessing/calculating health benefits?
- What are the ecological benefits?[42]
- What types of studies will form the basis and what key assumptions or data will be used to apply estimates to this case? What are the data sources? Are these original studies?
- Note: Distributional health benefits may need particular focus. For example, children's health benefits or costs may need special consideration as they are incorporated into the economic analysis. Evaluating these benefits may be warranted, even in cases where the Executive Order on Children's Health (E.O. 13045) is not triggered, but the additional information would be of particular interest.
- Note: health risk assessment is discussed above in the Scientific Analysis section.
- Compliance Rates
  - How will realistic compliance rates or emissions rates be projected in the "no regulation" scenario (base case, in the absence of the regulation)?
  - Is 100% compliance with existing standards assumed?
  - What assumptions will be made about changes in technology, compliance rates, and emissions that would occur in the future even without the action being considered (i.e., to what extent would improvements occur anyway)?

[42]See "A Framework for the Economic Assessment of Ecological Benefits" (http://www.epa.gov/osa/spc/htm/eaeb.htm)

- Will it consider the possibility of some parties going beyond the new standards?

4. **Cross-Media Issues**

   - Will the analysis include impacts of any secondary, adverse environmental impacts (e.g., increased emissions of other air pollutants from use of control devices, or energy to operate; additional discharges to water; additional solid or hazardous waste)?

5. **Results and Option Selection**

   - How will results be summarized?
   - Will various alternatives be compared in a table?
   - Will incremental costs and/or benefits be shown, indicating the additional costs or benefits resulting from choosing one alternative vs. another?

6. **Other Analyses Required to Support Action Development Where Economics May be Important**

For each relevant area of analysis, the Blueprint should address plans for the following:

Data Gathering

A. Identify the economic information (e.g., research, analyses and data collection efforts) needed to inform the decision and to measure the environmental or public health outcomes of the decision. For these informational needs,

   - What data are already available or expected soon?
   - Should a literature review be conducted?
   - What are the critical data gaps and methods for filling those gaps?

B. Identify the schedule/timeline, data sources, and parties responsible for obtaining this information:

   - What types of economic expertise are needed? Has peer input been considered? Who are the recognized experts, and will their judgments be elicited? Is this expertise available within the Agency? Outside the Agency?
   - Is an Information Collection Request (ICR) needed?[43]

[43] See "ICR Handbook: EPA's Guide to Writing Information Collection Requests Under the Paperwork Reduction Act of 1995" and "The Paperwork Reduction Act of 1995: Implementing Guidance for OMB Review of Agency Information Collection" (http://intranet.epa.gov/icrintra/index.html)

[44] See "2002 Information Quality Guidelines" (http://www.epa.gov/quality/informationguidelines)

[45] See "Peer Review Handbook—2nd Edition" (http://www.epa.gov/osp/spc/2peerrev.htm); and "Peer Review in the Rulemaking Process Fact Sheet" (http://intranet.epa.gov/adplibrary).

[46] See "2002 Information Quality Guidelines" (http://www.epa.gov/quality/informationguidelines)

C. Describe the plans for ensuring that the information used in the decision meets the Agency's Information Quality Guidelines[44] and the Peer Review Policy.[45]

- What are the plans for meeting the Agency's Information Quality Guidelines[46]? What steps have been taken so far?
- What are the plans for meeting the Agency's Peer Review Policy for peer review of major economic products? Include a schedule for the review and identify the resources that will be needed.

Analysis

- What analytic results are already available or expected soon? What kind of analysis is still needed? Are the information products and analytical tools already available, being developed, or do they need to be initiated? If not completed, will they be completed on time?
- What are the detailed plans for the analysis? What are the assumptions being made and why? Is there strong rationale for these assumptions or are they unavoidable?
- How sufficient or advanced are the economics in this area? What economic issues remain controversial and how will they be handled? What are the significant uncertainties or controversies in data, analytic tools, assumptions, and theories? Is there any a lack of agreement in the economic community about any of the economic issues? (e.g., including anticipated/potential use of default assumptions, such as discount rates or ecological valuations)
- Are there any significant tradeoffs between quality analysis and resources or timing? Will the quality of underlying economics be affected by other constraints? If so, this should be discussed, with an indication of any options for mitigating these impacts.
- What additional data or studies are needed to reduce the level of uncertainty and to obtain more widespread agreement on major assumptions?

Presentation and Communicating Uncertainty

- How will uncertainty and variability in economic analysis results be characterized in summaries of results?
  - Will EPA use ranges to express uncertainty?
  - Will sensitivity analysis be used for certain parameters? If so, which ones?
  - Will probabilistic approaches be used, such as Monte Carlo simulation?
  - Which costs, benefits, or other values will be shown as point estimates, ranges, central point and range, multiple point estimates (e.g., scenarios), or probability or frequency distributions?